# DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH

# NATIONAL ADVISORY COUNCIL FOR COMPLEMENTARY AND INTEGRATIVE HEALTH MINUTES OF THE SIXTY-EIGHTH MEETING October 5, 2018

#### **NACCIH Members Present**

- Dr. Belinda Anderson, New York, NY
- Dr. Martin Blaser, New York, NY
- Dr. Alice Clark, University, MS
- Dr. Lynn DeBar, Seattle, WA
- Dr. Tracy Gaudet, Washington, DC
- Dr. Steven George, Durham, NC
- Dr. Christine Goertz, Davenport, IA
- Dr. Joel Greenspan, Baltimore, MD
- Dr. Bin He, Pittsburg, PA<sup>1</sup>
- Dr. Patricia Herman, Santa Monica, CA
- Dr. Susmita Kashikar-Zuck, Cincinnati, OH
- Dr. Jean King, Worcester, MA
- Dr. Helene Langevin, Boston, MA
- Dr. John MacMillan, Santa Cruz, CA
- Dr. Cynthia Price, Seattle, WA
- Dr. Eric Schoomaker, Bethesda, MD<sup>1</sup>
- Dr. Barbara Timmermann, KS
- Dr. Gloria Yeh, Boston, MA

#### **Speakers**

Dr. Arlene Bierman, MD

Dr. Joseph Chin, MD

Dr. Roger Chou, OR

### **Members of the Public:**

Beth Clay Taylor Walsh

#### I. Closed Session

The first portion of the sixty-eighth meeting of the National Advisory Council for Complementary and Integrative Health (NACCIH) was closed to the public, in accordance with the provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

<sup>&</sup>lt;sup>1</sup>Telephone

A total of 99 applications were assigned to NCCIH. Applications that were noncompetitive, not discussed, or not recommended for further consideration by the scientific review groups were not considered by Council.

Council agreed with staff recommendations on 48 applications, requesting \$17,081,098 in total costs.

#### II. Call To Order

The open session convened at 9:35 a.m. Dr. Partap Khalsa, NACCIH Executive Secretary, called the meeting to order. The minutes of the June 2018 Council meeting were approved unanimously.

# III. NCCIH Director's Report

NCCIH Acting Director Dr. David Shurtleff welcomed a new Council member, Dr. Barbara Timmermann.

Dr. Helene Langevin will become NCCIH director in late November. Dr. Shurtleff said that having such a world-renowned researcher take on the leadership of NCCIH is a remarkable moment in the Center's history. He thanked Council for their advice and NCCIH staff for their support and input during his service as acting director. Dr. Shurtleff will stay at NCCIH as deputy director, and Dr. Wendy Weber, who has served as acting deputy director in addition to her role as branch chief of the Clinical Research in Complementary and Integrative Health Branch in the Division of Extramural Research (DER), will continue in the latter position.

NIH has received its full year appropriation for Fiscal Year (FY) 2019. The budget includes a 5.4 percent increase over FY 2018 for NIH as a whole and a 3.02 percent increase for NCCIH. The increases in funding for FY 2018 and FY 2019 have enabled NCCIH to fund a larger number of new, competing projects.

The opioid bill (H.R. 6) passed the House and has been cleared by the Senate. The bill is intended to improve the ability of the Department of Health and Human Services (HHS) to respond to the opioid epidemic. Language in the bill refers to approaches studied by NCCIH.

Dr. Khalsa is leading the search committee for the director of the Office of Pain Policy and Planning. NIH Director Dr. Francis Collins recently issued an important statement on protecting the integrity of U.S. biomedical research. The NIH BRAIN Initiative has passed its halfway point; its second half, called BRAIN 2.0, which will emphasize discovery-driven science, is now being planned. The NIH Health Care Systems Research Collaboratory, which supports large-scale studies conducted in collaboration with health care systems, has initiated five new projects.

The NIH HEAL (Helping to End Addiction Long-term) Initiative has issued multiple funding opportunity announcements (FOAs) related to the development of effective nonopioid therapies for pain or improved treatment of opioid use disorder (OUD). The Pain Management Collaboratory, an NCCIH-supported group of pragmatic trials on nonpharmacologic approaches for managing pain and other comorbid conditions in the veteran or military health care systems, held its steering committee meeting on September 17-18. All 11 Collaboratory projects are midway through the 2-year planning phase. The Joint Commission, which accredits hospitals,

has published an advisory on nonpharmacologic and nonopioid solutions for pain management, which mentions the use of several approaches NCCIH studies.

Highlights of recent NCCIH-funded research include:

- Two analyses of data on the prevalence and profile of high-impact chronic pain, which are part of an effort to reconceptualize pain based on disability as well as duration.
- An analysis of the use of opioids and nonpharmacologic modalities for low-back pain in Veterans Health Administration facilities, which showed that nonpharmacologic modalities were frequently used but patterns of use differed among individuals and facilities.
- A qualitative study of how healthy volunteers and fibromyalgia patients rate experimental pain, which will help to inform future studies that use pain ratings.
- A study from the intramural research program that identified a key role for dual leucine zipper kinase in neuropathic pain. This finding is important because it identified a potential nonopioid target for pain therapy and demonstrated the role of the neuroimmune system in the development of hyperalgesia.

Recent NCCIH events include new FOAs for clinician-scientist career development and for research on music and health; the launch and widespread use of the HerbList<sup>TM</sup> app; and an NCCIH satellite symposium on chronic pain and complementary health approaches at the International Association for the Study of Pain World Congress on Pain in Boston. Dr. Shurtleff thanked Dr. Wen Chen, acting branch chief of the DER's Basic and Mechanistic Research in Complementary and Integrative Health Branch, for playing a leadership role in organizing the satellite symposium. The National Academy of Sciences will hold an important workshop on nonpharmacologic approaches to pain management in December.

NCCIH continues its efforts to support its mission through social media. In recognition of Pain Awareness Month in September, NCCIH held a campaign called #HopeThroughResearch on Twitter, in which pain researchers discussed their work in short videos. The campaign attracted much interest and engagement. NCCIH was among the leading influencers at a National Institute of Neurological Disorders and Stroke–led Twitter chat on pain. In recognition of National Yoga Month, NCCIH conducted a robust campaign on Instagram where people submitted photos and stories explaining why they practice yoga.

Events will be held to commemorate NCCIH's twentieth anniversary in FY 2019. The kickoff for the anniversary year will be the annual Stephen E. Straus Distinguished Lecture in the Science of Complementary Therapies, to be presented this year by *ex officio* Council member Dr. Tracy Gaudet. Dr. Gaudet will speak on November 29 on "Transforming Veterans' Health: Implementing a Whole Health System of Care."

# IV. Division of Intramural Research Report 2018

Dr. M. Catherine Bushnell, Scientific Director of the Division of Intramural Research (DIR), presented the Division's annual report to Council. Major accomplishments included:

• Hiring Dr. Magdalena Naylor, who is internationally known for her work on pain management and cognitive behavioral therapy (CBT), as Clinical Director of the DIR and Chief of the Clinical Investigations Branch.

- Leading an NIH-wide effort to create a Pain Center within the NIH Clinical Center. Although this proposal did not receive HEAL funding, it is moving forward as a grassroots effort with support from multiple institutes and centers (ICs). Three initial projects are being launched:
  - o Project 1: Understanding mechanisms of chronic pain utilizing a hematopoietic stem cell transplant model in patients with sickle cell disease. The goal is to understand why half of sickle cell patients successfully treated by hematopoietic stem cell transplant still have pain. The findings may enhance understanding of the transition from acute pain to chronic pain.
  - Project 2: Psychosocial and neural factors that shape responses to third molar extraction surgery and predict postsurgical pain and opioid use. Young people who have third molar extractions are of interest because this surgery is often their first introduction to opioids.
  - o **Project 3: Study of patients with rare somatosensory processing disorders to uncover new mechanisms in pain genetics and neurobiology.** This project is already under way, focusing on patients with knockouts in the *Piezo2* gene as well as a patient with an unusual type of congenital insensitivity to pain.

Additional studies in the pipeline include a project on dopaminergic modulation of brain activation using simultaneous positron emission tomography/pharmacologic magnetic resonance imaging and a project to be led by Dr. Naylor on whether CBT for pain management can enhance endogenous opioid function in patients with musculoskeletal pain. A small house on the NIH campus is being renovated to provide office space for the Pain Center.

# V. Bidirectional Control of Pain in the Central Amygdala

Dr. Yarimar Carrasquillo, a tenure-track investigator in the DIR, summarized her laboratory's research on pain modulation. It is well known that pain can be modulated up and down by various factors, but the underlying brain mechanisms have not been established. Dr. Carrasquillo's lab uses animal models to address this. The focus is on the central amygdala of the brain. Previous research indicated that the amygdala can have both pronociceptive and antinociceptive roles.

Two types of cells—those that express somatostatin and those that express protein kinase C-delta (PKCδ)—constitute most of the population of cells in the central amygdala. Dr. Carrasquillo and her colleagues have used molecular genetic approaches, in combination with a mouse model of neuropathic pain, to target specific populations of cells to assess their relationship to pain hypersensitivity. They found that cells that express PKCδ are associated with nerve injury-induced pain and confirmed this finding by showing that a pharmacologic agent that inhibits PKCδ cells inhibits the behavioral pain response. The cells that express somatostatin show decreased expression in the mouse model of neuropathic pain, compared to control mice, and chemical inhibition of the somatostatin-expressing cells induces tactile hypersensitivity in the absence of injury. Thus, the central amygdala can modulate pain through the recruitment or inhibition of these two cell types, which have opposite effects.

Dr. Carrasquillo and her colleagues are now investigating nociceptive inputs to the central amygdala, primarily from the parabrachial nucleus, and outputs to multiple brain regions.

They've developed robust evidence of projection to the zona incerta, a region known to be involved in pain, and will investigate this relationship further using optogenetic and chemogenetic tools.

**Discussion:** Dr. Blaser complimented Dr. Carrasquillo on the elegance of her work and asked about the roles of the amygdalas on the two sides of the brain. Dr. Carrasquillo explained that the right amygdala modulates pain, and the left does not. The role of the left amygdala is currently unknown. Dr. King said that this work serves as a reminder of the importance of basic science and asked whether modulation of somatostatin would decrease pain and whether the known roles of the amygdala in fear and emotion relate to its role in pain. Dr. Carrasquillo said that her group hopes to tackle these important questions. The cells that express somatostatin are the more interesting ones. Study of the fear/pain connection will require behavioral models that produce robust, consistent phenotypes. Dr. Shurtleff complimented Dr. Carrasquillo's work and said he hopes it is published soon.

# VI: Concept Clearances

### Mechanisms Underlying Analgesic Properties of Terpenes and Minor Cannabinoids

The cannabis plant contains approximately 110 cannabinoids and 120 terpenes. Compounds in both groups may have analgesic effects. However, very few have been extensively studied.

This concept, presented by NCCIH Program Director Dr. Inna Belfer, has the following goals:

- To encourage research on terpenes and minor cannabinoids related to pain, nociception, and inflammation
- To support highly innovative basic and/or mechanistic studies in appropriate model organisms and/or human subjects aiming to identify, demonstrate, and predict if terpenes and minor cannabinoids can help treat pain
- To encourage interdisciplinary collaborations by experts from multiple fields.

**Discussion:** Dr. Timmermann said that the initiative is of great importance but recommended concentrating exclusively on cannabinoids. She also recommended changing the title of the initiative to refer to "nonaddictive" rather than "minor" cannabinoids. Dr. Alice Clark suggested just referring to "cannabinoids" because whether particular compounds are addictive may not be known. Dr. Shurtleff explained that NCCIH's intent was to cast a wide net because it's not yet clear which components of cannabis contribute to its analgesic effect, and interactions among constituents of the plant may be important. Dr. Timmermann pointed out that terpenes are not unique to cannabis; they are also found in fruits and vegetables. Dr. MacMillan suggested that different investigators could work on different compounds depending on what proposals NCCIH receives. Dr. Alice Clark suggested including terpenes from cannabis that may influence the effects of cannabinoids but not terpenes in general. Dr. Shurtleff agreed that this might be a suitable compromise and said there would be further discussion about which compounds to include before the FOA is issued. Dr. George suggested that NCCIH may want to focus on models that show promise for translation.

A motion to approve the concept was made, seconded, and passed unanimously.

# **Emotional Well-Being: High-Priority Research Networks**

Dr. Emmeline Edwards, Director of the DER, presented this concept, which responds to the April 2018 NIH roundtable that identified gaps and opportunities in research on emotional well-being, including the need to:

- Increase the understanding of the fundamental constituents of emotional well-being across the lifespan and among various subgroups
- Refine and implement scientifically based prevention strategies to enhance emotional well-being
- Develop measurement methodologies to optimize and scale up emotional well-being interventions for treatment and prevention of burnout, stress, pain, and mental health symptoms in at-risk populations.

The proposed initiative is intended to solicit applications that focus on developing resources. It would support research networks through meetings, conferences, small-scale pilot research, multidisciplinary cross training, and information dissemination to foster growth and development of research in five priority areas: ontology, mechanisms, biomarkers, prevention research, and technology and outcome measure development for mechanistic studies. Drs. Merav Sabri and Dave Clark would be the program directors.

**Discussion:** Dr. Shurtleff said that this initiative is intended to be a preliminary step before launching into research agendas. Dr. Kashikar-Zuck expressed strong support for the concept. She noted that at her pediatric hospital, there is talk about integrating emotional well-being into primary care; this initiative could be helpful, especially with regard to measurement. Dr. Weber said that integrating assessment of emotional well-being into care is a wonderful idea but might have unintended consequences, as was the case with treating pain as a vital sign. She said that it's important to be able to advise providers about what to do with the results of an emotional well-being assessment. Dr. Herman said that integrating emotional well-being into care will require a large systems change. For example, more behavioral health interventions and social workers might need to be available. Dr. Gaudet said that her office has implementation experience in this area and could contribute to the thinking on this effort. Dr. Price expressed strong support for the concept and said that many of the beneficial effects of complementary approaches may be based on improved emotional well-being.

A motion to approve the concept was made, seconded, and passed unanimously.

#### **NCCIH HEAL Initiatives**

Dr. Wendy Weber explained that NCCIH is participating in multiple components of the HEAL Initiative related both to OUD and pain management. NCCIH is administering six awards on integrating behavioral approaches with medication-assisted therapy (MAT) for OUD to improve adherence to therapy. These projects involve partnering with state agencies participating in the Substance Abuse and Mental Health Services Administration (SAMHSA) State Targeted Response to the Opioid Crisis Grants initiative. NCCIH is also participating in HEAL Initiative FOAs relevant to the NCCIH mission that are administered by other ICs.

The current concept involves two new proposed NCCIH-led initiatives within the context of HEAL. Council voted on the two components separately.

The first initiative involves pragmatic and implementation studies for the management of pain to reduce opioid prescribing. The studies must be embedded in health care systems and would

involve system changes to improve adherence to evidence-based guidelines for pain management and integration of evidence-based approaches for pain management into health care delivery. The intent is to inform health care policymakers about coverage decisions and how to implement pain management approaches. In addition to the individual trials, NCCIH would support a central resource center to assist trials in achieving rigor and reaching the project milestones. This initiative would involve partnering with other ICs and with agencies outside NIH, and the cooperative agreement funding mechanism would be used.

A motion to approve the concept was made, seconded, and passed unanimously.

The second initiative involves expanding NCCIH's involvement in behavioral research to improve MAT for OUD. Currently, NCCIH is funding six projects in this area, most of which are pilot studies. The new initiative would fund larger studies and allow researchers to scale up studies already in progress. NCCIH is proposing to support studies to (1) examine the impact of integrating evidence-based behavior interventions for treating co-occurring conditions, such as pain, depression, or sleep disorders, with MAT to determine if this improves adherence to MAT and prevents OUD relapse; and (2) evaluate the impact of behavioral interventions to improve access to, delivery of, and adherence to MAT.

**Discussion:** Dr. Price suggested that this initiative should address the integration of behavioral interventions into conventional care. Dr. Weber said that this would be possible.

A motion to approve the concept was made, seconded, and passed unanimously.

# VII: Recognition of Council Members With Expiring Terms

Dr. Shurtleff thanked the outgoing Council members, Drs. Blaser, Alice Clark, and Goertz, for their contributions and presented certificates to each of them.

### VIII. Interaction Between Evidence-Based Guidelines and NCCIH Research Priorities

#### Introduction

Dr. Shurtleff introduced the panelists for this presentation, noting that the opioid crisis has motivated Federal agencies to work together and with organizations that develop evidence-based guidelines. As NCCIH increasingly engages with other organizations, there is a need for a deeper understanding of their work.

#### Systematic Reviews, Guideline Development, and NCCIH Research Priorities

Dr. Roger Chou, Professor of Medicine at Oregon Health & Science University and Director of the Pacific Northwest Evidence-based Practice Center, explained that evidence-based guidelines are important because clinical practice is often inconsistent with evidence. Guidelines can help to reduce practice variations, improve patient outcomes, and inform development of quality measures. They can have major impacts on clinical practice and policy.

Evidence-based guidelines make use of an unbiased systematic review of the evidence, focus on the best evidence, clearly link evidence and clinical action, and help clinicians apply evidence to individual patients. They are not intended to force practitioners to abandon clinical judgment and are not necessarily based only on randomized controlled trials (RCTs). A systematic review of comparative effectiveness research is the most reliable way to identify benefits and risks

associated with various treatment options. Systematic reviews use explicit methods for identifying, including/excluding, and rating the validity of studies and synthesizing the evidence.

The Agency for Healthcare Research and Quality (AHRQ) has designated several centers across the country as Evidence-based Practice Centers based on their expertise in conducting systematic reviews. Dr. Chou's center has expertise in topics relevant to NCCIH and has conducted reviews that served as the basis for guidelines on low-back pain and opioids for chronic pain.

Nonpharmacologic therapies are difficult to evaluate in clinical trials and systematic reviews because they cannot be completely masked and because of variability in techniques and the intensity of treatments. In general, effects of nonpharmacologic approaches are small and short-term, with limited effects on function. Because systematic reviews of nonpharmacologic therapies may evaluate multiple approaches and make multiple comparisons, efforts are being made to present the findings in forms that are easy for practitioners to use, such as a tableau dashboard or an app.

Future research needs include improved standardization of interventions and standardization of research protocols for collecting and reporting outcomes, including harms. Nonpharmacologic interventions need to be compared with pharmacologic ones, and studies in subpopulations are needed. Both traditional explanatory and pragmatic trials are needed to inform practice. Emerging areas include the development of easily updated "living" systematic reviews and techniques for evaluating complex interventions. Support is needed for innovative methods for conducting, maintaining, and presenting systematic reviews of complementary therapies.

# **Agency for Healthcare Research and Quality**

Dr. Arlene Bierman, Director of the Center for Evidence and Practice Improvement at the AHRQ, explained the AHRQ's role in evidence assessment. The AHRQ's mission is to produce evidence to make health care safer, high quality, and more accessible, equitable, and affordable, and to work with HHS and other partners to ensure that evidence is available and used. The AHRQ conducts research to help health care systems deliver safe and effective care, bridging the gap between research and practice.

Systematic reviews play a key role in evidence-based decisionmaking, but not all systematic reviews are of high quality. Low-quality systematic reviews can result in biased interpretation, an incomplete picture of the evidence, inadequate assessment, and inaccurate or misleading conclusions. Sometimes, the results of a systematic review may be definitive enough that additional clinical trials are not needed, and more could be gained by moving on to other questions.

The AHRQ's evidence reviews are stakeholder-driven, scientifically rigorous, and independent and unbiased. The AHRQ produces evidence reports at three different levels of complexity and grades the strength of evidence for major comparisons and outcomes. Federal partners can enter into interagency agreements with the AHRQ to produce an evidence report. The AHRQ also develops clinical decision support (CDS) tools to help practitioners put evidence into practice. In response to a question from Dr. Shurtleff about how widely the CDS tools are disseminated, Dr. Bierman said that the opioid CDS tool that she showed as an example is a prototype designed for the benefit of technology people in health care systems, who can download the code and adapt it for their systems. This work is part of a research portfolio on CDS with many partners. AHRQ has built an infrastructure that other agencies and health systems can share.

One group that makes use of AHRQ evidence reviews is the U.S. Preventive Services Task Force, an independent panel of non-Federal experts that makes evidence-based recommendations about clinical preventive services in primary care. In some cases, the recommendations are "I" statements (where "I" stands for Insufficient Evidence). An "I" recommendation is an indicator of an evidence gap that needs to be filled. The AHRQ responds to this need by meeting regularly with the NIH Office of Disease Prevention to inform them about "I" statements. This process has stimulated new NIH research to fill evidence gaps, such as a research initiative on screening children for autism.

**Discussion:** Dr. Blaser asked how often the U.S. Preventive Services task force gives a "D" recommendation (a recommendation against the use of a service because it has no net benefit or its harms outweigh its benefits). Dr. Bierman said that there have been a few, some of which are controversial. There are also instances where a "D" recommendation has been made for certain population subgroups, although the same service may be recommended for others.

### **Medicare Coverage Basics**

Dr. Joseph Chin, Deputy Director of the Coverage and Analysis Group at the Center for Clinical Standards and Quality of the Centers for Medicare and Medicaid Services (CMS), explained that Medicare uses scientific evidence as a basis for decisions about coverage. Medicare, which provides health care coverage for 58 million Americans, pays for reasonable and necessary services for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Coverage determinations address whether the evidence is sufficient to conclude that an item (drug or device) or service improves clinically meaningful health outcomes for the Medicare population. The quality, strength, and totality of evidence are considered, with a focus on important patient-centered outcomes.

Medicare was originally established as inpatient insurance and therefore was physician focused. Currently, although some other types of providers, such as nurse practitioners and physician assistants, are eligible, there are some constraints on the types of providers whose services are covered. Some providers, such as health counselors, cannot bill Medicare directly for their services but must bill through the office of a physician with whom they are associated. Medicare coverage is also limited in terms of settings. Although inpatient, outpatient, and long-term care facilities are eligible, community-centered services currently are not. Coverage for preventive services was historically excluded from Medicare, but since 2008 many preventive services with "A" or "B" recommendations have been added on an individual basis.

Medicare does many assessments to support coverage determinations internally but has a mechanism to commission assessments, almost always through AHRQ. When evidence is insufficient for a positive decision about coverage, services may be covered in the context of approved clinical studies or with the collection of additional clinical data. This is called coverage with evidence development (CED). One reason why evidence is often insufficient for coverage determinations is that early studies of a new drug or procedure are typically age-limited and include few people from the Medicare population.

The Medicare national coverage process typically takes 9 months, after which decisions are monitored to assess their impact and to see whether they continue to be consistent with the evidence. With the current emphasis on the opioid crisis, Medicare has looked at nonpharmacologic interventions to see how policies are aligned with their use.

**Discussion:** Dr. Goertz commented that CMS and many insurers have barriers to payment for nonpharmacologic interventions such as acupuncture and chiropractic care. Dr. Chin explained that many nonpharmacologic interventions can be covered by Medicare. In situations where Medicare coverage determinations may not be aligned with the evidence, any stakeholder can request a reconsideration. Dr. Shurtleff asked how CMS prioritizes conditions and interventions for coverage decisions. Dr. Chin replied that the impact on the Medicare population is crucial. For example, low-back pain, a common and debilitating condition, would be high priority. Other factors include effectiveness, whether there is an existing treatment, whether Medicare has an existing position, and whether that position is consistent with current evidence.

Dr. Khalsa asked Dr. Bierman whether it's possible to determine at the time of a systematic review that the evidence for a particular decision is sufficient or whether this decision can only be made in hindsight. Dr. Bierman said that if there is high-quality evidence with narrow confidence intervals and clinically meaningful effects, a decision may be possible. Dr. Shurtleff said that feedback about when the evidence on the effectiveness of a particular therapy is adequate could help NIH set research priorities.

Dr. DeBar asked whether it is true that once Medicare approves a therapy, it is always covered. Dr. Chin replied that a decision might be reversed over safety issues. However, if a treatment is ineffective, providers usually stop using it. Dr. Weber asked whether implementation science is conducted on CDS tools before they are made available. Dr. Bierman said that AHRQ CDS tools are piloted and evaluated but others may not be. NCCIH program director Dr. Dave Clark returned to the topic of determining when evidence is sufficient to move an intervention into widespread use. Dr. Bierman said that AHRQ will publish guidelines on the strength of evidence for implementation.

Dr. Shurtleff asked whether, in a learning health care system, there is any followup after a practice is implemented. Dr. Chou said that some studies have looked at how guidelines are implemented, but unfortunately, many groups that produce guidelines focus only on development rather than implementation. Dr. Bierman said that often there is a lack of evidence on how to increase the use of an intervention by health care providers. AHRQ is interested in working in this area. Dr. Chin said that for Medicare, the CED process is helpful in determining how well an intervention works in clinical practice. Dr. Bierman added that disease registries are another helpful source of information for decisions about which practices to implement.

# VI. Public Comment and Adjournment

Ms. Beth Clay, director of government relations for the International Chiropractors Association (ICA), noted that the only chiropractor on the Council has completed her term and expressed the hope that she would be replaced by another equally qualified person from her profession. She also asked about public members or patient advocates on the Council. She suggested that NIH could benefit from having a clinical center for pain and emotional well-being for employees, patients, and patient families, which could serve as a center of excellence for methods development and testing. Ms. Clay suggested that when H.R. 6 becomes law, NCCIH will play a critical role in its implementation because the guidelines to be developed will rely heavily on NCCIH research, and she urged NCCIH to engage actively in this process. She noted that patients often make health care decisions based on what services are covered by their insurance, so it is important to enhance coverage of services like acupuncture and massage therapy so that

people will use them for pain management. Ms. Clay suggested that NCCIH needs more input from the autism community and should do more research on autism.

The meeting was adjourned at 3:15 p.m.

We hereby certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.

Partap Khalsa, D.C., Ph.D., D.A.B.C.O. Executive Secretary National Advisory Council for Complementary and Integrative Health David Shurtleff, Ph.D. Acting Chairperson National Advisory Council for Complementary and Integrative Health